K013631

NOV 2 0 2001

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for eFilm Video™, in accordance with SMDA 1990.

Date Prepared:	Oct 26, 2001
Submitted By:	eFilm™ Medical Inc. 500 University Ave, Suite 300, Toronto, Ontario Canada M5G 1V7
Contact Name:	Joseph A. Thomas
Contact Email:	joseph.thomas@efilm.ca
Contact Telephone:	(416) 204 9664 ext 291
Contact Fax:	(416) 204 9442
Device Trade Name:	eFilm Video™
Device Common Name:	Video Capture System
Regulation Number:	892.2030
Device Classification:	Class II
Name:	Medical Image Digitizer
Predicate Device:	CHILI Video/Pro Video
Predicate Device Manufacturer:	STEINBEIS-TRANSFERZENTRUM MEDIZINISCHE INFORMATIK
Predicate Device 510(k) Number:	K000411
Date Received:	02/08/2000
Decision Date:	04/14/2000
Decision:	Substantially Equivalent
Panel Code Device Reviewed by:	Radiology
Panel Code Device Classified by:	Radiology
Product Code:	LMA
Regulation Number	892.2030
Classification:	Class II

5K-82

Device Description

eFilm Video™ is a software application that is used for capturing video streams from analogue medical image acquisition devices with video outputs and converting these streams to DICOM compliant cine loops. Users may capture single stills or consecutive images and save them as DICOM files that can be viewed and manipulated in a picture archiving and communications viewing application.

Indications For Use

eFilm Video™ is a software application that captures video streams from analogue medical image acquisition devices with video outputs and converts these streams to DICOM compliant cine loops. These images can be sent to DICOM compliant devices for display and processing. Users may also input patient demographic information that is related to the captured images.

RA II

Typical users of eFilm Video™ are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Technological Characteristics

eFilm Video™ performs the same functions relating to image acquisition as the predicate device. eFilm Video™ operates in the same environment as the predicate device and raises no new questions of efficacy or substantial risk and therefore is substantially equivalent to the predicate device.

eFilm Video™ does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed and/or printed.

Testing

eFilm Video™ is tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part of eFilm Medical Inc.'s software development process as described in the SOP-01: Product Development Process

Conclusion

The 510(k) premarket notification for eFilm Video™ contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

1. eFilm Video™ has been and will continue to be manufactured according to the voluntary standards listed in the Voluntary Standards section (4.1) of this submission.

2. This submission contains the result of a hazard analysis and all potential hazards have been classified as minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

EFilm Medical Inc.™
% Mr. Ned Devine
Program Manager
Entela Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K013631
Trade/Device Name: eFilm Video™
Video Capture System
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: October 26, 2001
Received: November 5, 2001

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K013631

NOV 2 0 2001

Device Name: eFilm Video™

Indications for Use:

eFilm Video™ is a software application that captures video streams from analogue medical image acquisition devices with video outputs and converts these streams to DICOM compliant cine loops. These images can be sent to DICOM compliant devices for display and processing. Users may also input patient demographic information that is related to the captured images.

Typical users of eFilm Video™ are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109): ✓

OR

Over the Counter Use (optional Format 1-2-96): ____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013631